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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,698	06/26/2007	Guilaine Argoud-Puy	4-33639A	2237

7590 07/22/2008

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH,INC
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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,698	ARGOUD-PUY ET AL.	
	Examiner	Art Unit	
	PADMA v. BASKAR	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESTRICTION

1 Applicants preliminary amendment filed on 1/13/06 has been entered.
Claims 3, 4, 5, and 7 have been amended.
Claims 1-18 are pending in the application.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I claim(s) 1 -2 (in part) 2, 3-6, 7 and 8 (in part) drawn to and an isolated polypeptide CPP 30 and a method of screening for and/or diagnosis of a cardiovascular disorder in a subject, comprising the steps of detecting and/or quantifying the level of Cardiovascular disorder Plasma Polypeptide (CPP) CPP 30

Group II claim(s) 1, 2 (in part) 3-6 and 7 drawn to a method of screening for and/or diagnosis of a cardiovascular disorder in a subject, comprising the steps of: detecting and/or quantifying the level of a polypeptide CPP 31-148.
(Further restriction to one CPP is required , see paragraph # 4)

Group III , claim(s) 8 (in Part) and 14 (in part) drawn to an isolated polypeptide comprising the amino acid sequence CPP 31-148.
(Further restriction to one CPP is required , see paragraph # 4)

Group IV claim(s) 9 (in Part) and 10-12 drawn to CPP antibody that selectively binds to a polypeptide comprising the amino acid sequence CPP 30-148 and a method of binding an antibody to said CPP comprising contacting the antibody with a biological sample.
(Further restriction to one CPP is required , see paragraph # 4)

Group V claim(s) 13 drawn to a method of identifying a CPP modulator comprising contacting a test compound with a polypeptide selected from the group consisting of CPP 30-148.
(Further restriction to one CPP is required , see paragraph # 4)

Group VI claim(s) 15 drawn to a polynucleotide encoding CPP 30-148.
(Further restriction to one CPP is required , see paragraph # 4)

Groups VII claim(s) 16-17 drawn to a method of identifying a modulator of a cardiovascular disorder comprising the steps of adminstering s candidate agent and detecting and quantifying CPP 30-148.
(Further restriction to one CPP is required , see paragraph # 4)

Groups VIII claim(s) 18 drawn to a method for monitoring the efficacy of a treatment of a subject having or at risk of developing a cardiovascular disorder with an agent, the method comprising obtaining a pre-administration biological sample from the subject prior to administration of the agent and detecting and/or quantifying the level of at least CPP 30-148 in the biological sample.
(Further restriction to one CPP is required , see paragraph # 4)

3. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special feature technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to peptides, nucleic acids and antibodies and methods of using peptides, nucleic acids and antibodies. However, Rosen et al WO 01/12781A (see page 151, line 16 - page 154, line 8; page 7, line 26 - page 11, line 10 and sequence 30) or Averback et al US 2003/096756 A1 (see paragraph 0059,paragraph 0066,paragraph 0023) disclose isolated polypeptide CPP30 and method of diagnosing cardiovascular disorder. Therefore, the technical feature of linking groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

The technical feature of Group III is considered to be polypeptide that shares no common structure, property and function with Group VI since peptides contain amino acids and do not share the same or a corresponding technical feature with Group VII as DNA is made up of nucleic acid.

The technical feature of Group IV is considered to be antibody that shares no common structure, property and function from Inventions III and VII since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing and do not require each other for their practice.

The technical feature of linking Groups I (in part), II, V, VII, VIII is considered to be methods utilizing products (polypeptide or nucleic acid or antibody) that share no common structure, property and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among group IV.

Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

DISTINCT INVENTIONS

4. For each group of inventions II-VIII above, restriction to one of the following CPP is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions and one of CPP-30-148

Inventions CPP-30-148are not so linked as to under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed peptides CPP-30-148 share no common special technical feature because the peptides have no common structure (i.e., no common sequence) CPP-30-148represent sequences that share no common structure as polypeptides and the polynucleotides encoding them are not linked by the same the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, where structural identity is required, such as for hybridization or expression of protein or binding of antibody, each sequence appears perform a different function in that peptides elicit an antibody response and nucleic acids encode peptides that specifically bind to an antibody. Thus they share no

common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among inventions CPP-30-148

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed CPP-30-148 from groups II-VIII .

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Please note: Customer Number 75074 is associated with the address of record is NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC ,400 TECHNOLOGY SQUARE, CAMBRIDGE,MA 02139. However, the power of attorney is given to Customer Number 01095. Therefore, applicant is requested to clarify these issues.

7. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898.

Respectfully,

/Padma v Baskar/
Examiner, Art Unit 1645